

Notice of Allowability

Application No.

09/581,772

Examiner

Zachariah Lucas

Applicant(s)

O'HAGAN ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed on December 24, 2003.
2. ☒ The allowed claim(s) is/are 1,3-5,9-16,43,45-47,56-58,69-73 and 77-105.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2-19-2004</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Claims In the prior action mailed on August 27, 2003, claims 1-7, 10-16, 43-47, and 54-59, 69-80, 85-90, 94-97, and 100-102 were under consideration and rejected. It was indicated in the interview Summary of December 2, 2003, that these claims would be found allowable upon amendment to read on embodiments wherein the detergent is cationically charged, and the antigen is a polynucleotide antigen. These amendments were made to the claims in the Response filed on December 24, 2003. In view of these amendments, the claims currently pending (claims 1,3-5,9-16,43,45-47,56-58,69-73 and 77-105) in the application are allowed.

Claim Objections

2. Claim 69 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In view of the amendment of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

3. **(Prior Rejection-Withdrawn)** Claims 1-5, 7, 10-16, 44-47, 54, 56-57, 59, 69-80, 85-90, 94-97, and 100-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for microparticles with a polynucleotide antigen adsorbed to the surface wherein the detergent is cationically charged, does not reasonably provide enablement for such

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microparticles wherein the detergent is anionically charged. In view of the amendment of the claims such that they do not include anionically charged detergents, the rejection is withdrawn.

4. **(Prior Rejection-Withdrawn)** Claims 1-7, 10-16, 44-47, 54, 56-59, 69-80, 85-90, 94-97, and 100-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the microparticles comprising the polymers identified in claim 1, does not reasonably provide enablement for the claimed microparticles comprising any biodegradable polymer. This rejection is withdrawn because the Applicant has demonstrated that those in the art could practice the claimed invention. While the art show that certain biopolymers would not be operative, it is within the scope of the knowledge in the art to avoid such compositions. Therefore, undue experimentation is not required.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David B. Bonham on February 19, 2004.

The application has been amended as follows:

Claims 13, 14, 46, 47 are each amended such that the phrase "any of claim" in line 2 of the claims now reads --any one of claims- -.

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Claims 56, 58, 69-71, 7778, and 91 are each amended such that the phrase "any of claim" in line 1 of the claims now reads --any one of claims- -.

These amendments were made to the claims to correct the claim language such these multiple dependant claims depended from other claims in the alternative.

6. The following is an examiner's statement of reasons for allowance:

In the Response filed on June 16, 2003, the Applicant noted that the Bertling reference teaches away from the present invention by teaching that the use of cationically charged particles were not effective in the delivery of polynucleotides encoding antigens because, although the reference teaches that the particles could effectively deliver the polynucleotides, the reference also teaches that the polynucleotides so delivered were not transcriptionally active. In view of these teachings, it was indicated that those in the art would not have had a reasonable expectation of success in the use of microparticles such as those taught by Levy for the delivery of polynucleotides. The present claims, which read on microparticles comprising cationically charges detergents and with polynucleotides encoding antigens adsorbed to the microparticle surface, are therefore found allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

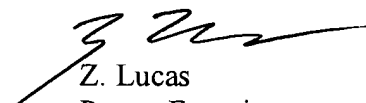
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Conclusion

7. Claims 1,3-5,9-16,43,45-47,56-58,69-73 and 77-105 are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 253/64
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600